Heraeus Kulzer, Inc.
Translux® Energy
510(K) Submission

AUG 3 0 2001

K012341

Summary of Safety and Effectiveness

Submitter:

Company Name: Heraeus Kulzer, Inc.

Address: 4315 South Lafayette Blvd.
South Bend, Indiana 46614

Telephone No.: 219-299-6662

Fax No.: 219-299-6616

Date: July 19, 2001

Name of Device

Classification Name: Ultraviolet activator for polymerization

Proprietary Name: Translux® Energy

Common Name: Light-curing unit

Predicate Device

Translux EC by Kulzer [K892456]

Description for the Premarket Notification

Translux Energy Light Curing Unit which is classified as an Ultraviolet Activator for Polymerization (21C.F.R. § 872.607).

Translux® Energy has the same intended use and is substantially equivalent to Kulzer's already 510(K)-cleared light-curing unit Translux® EC [K892456]. The Translux ® Energy is a further development of the Translux® EC light source to provide the patient and user with more comfortable handling and more favorable properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Ms. Cheryl V. Zimmerman
Manager of Quality Operations & Complaince
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, India 46614-2517

Re: K012341
Trade/Device Name: Translux® Energy
Regulation Number: 872.6070
Regulatory Class: II
Product Code: EBZ
Dated: July 20, 2001
Received: July 24, 2001

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012341

510(k) Number (if known): K012341

Device Name: Translux® Energy

Indications for Use:

Activator for light-induced intraoral polymerization of resin dental pit and fissure sealant, restorative materials, bonding , or luting materials.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ ___ ___

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012341